K013461 1/2

510(k) Summary Statement
ICN Photonics NLite System

JAN 17 2002

1. General Information

Submitter: ICN Photonics Ltd
Units 1&2 Heol Rhosyn
Dafen Parc
Llanelli, Carmarthenshire
Wales, UK, SA14 8QG

Contact Person: Dr Mike Kiernan – Director of Clinical Research

Summary Preparation Date: October 17th 2001

2. Names

Device Name: NLite System

Primary Classification Name: Laser Powered Surgical Instrument

3. Predicate Devices

- ICN Photonics Ltd NLite System, cleared August 2000, 510(k) approval number K000811.

4. Product Description

The NLite System is a flashlamp pumped, pulsed dye laser consisting of the following:

- Main laser console incorporating the laser resonator and external optics, high voltage delivery system, internal cooler, fluid circulation system, control unit and user interface;
- Flexible fibre optic delivery device and optical handpiece;
- Footswitch for pulsing control.

5. Indications for Use

The NLite system is indicated for use in the specialties of Dermatology and Plastic Surgery, and in particular for the treatment of wrinkles.

6. Rationale for Substantial Equivalence

The laser system described in this submission is cleared for marketing under 510(k) approval K000811, August 2000. No modifications to the laser system have been undertaken.

7. Safety and Efficacy Information

Clinical data has been provided to demonstrate that the NLite system is safe and effective for the described indications for use.

8. Conclusion

The NLite system has been found to be substantially equivalent to the predicate devices, specifically in technological design and operation and similar in nature to the desired physiological interactions. The design and manufacture of the device is in accordance with the relative international standards and the potential risk to operator and patient have been minimized.

The clinical data provided has demonstrated that the specific indications for use is met and the safety and efficacy of the system has been proved.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Michael Kiernan
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Units 1 & 2 Heol Rhosyn
Dafen Parc
Llanelli, Carmarthenshire
SA14 8QG
Wales, UK

JAN 1 7 2002

Re: K013461
Trade/Device Name: Nlite System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 17, 2001
Received: October 18, 2001

Dear Dr. Kiernan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement as Requested by FDA

510(k) Number (if known): ~~Not Known~~ K013461

Device Name: NLite System

Indications for Use:

The NLite System is indicated for use in Dermatological and Plastic Surgery applications and *this device is intended for use in the treatment of wrinkles.*

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013461

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)